

CLAIMS

- Sub 5
1. A pharmaceutical composition which comprises:
an essentially nonaqueous, liquid concentrate for oral administration
comprising an amount of sertraline or a pharmaceutically acceptable salt thereof and
one or more essentially nonaqueous pharmaceutically acceptable excipients; wherein
at least one of the excipients is liquid.
 2. The composition of claim 1 which comprises a therapeutically effective amount
of sertraline or a pharmaceutically acceptable salt thereof.
 3. The composition of claim 2 wherein the pharmaceutically acceptable salt of
10 sertraline is the hydrochloride salt or the mesylate salt.
 4. The composition of claim 1 wherein the excipients are selected from the
group consisting of ethanol, glycerin, polyethylene glycol and propylene glycols.
 5. The composition of claim 4 wherein the excipients are ethanol and glycerin.
 6. The composition of claim 1 wherein the concentrate comprises sertraline
15 hydrochloride in an amount of about 15 to about 30 mg/ml and wherein the excipients
are ethanol and glycerin in an amount of about 8 to about 20% ethanol (by weight) in
glycerin.
 7. The composition of claim 6 wherein the concentrate further comprises one or
more flavoring agents and one or more pharmaceutically acceptable preservatives.
 - 20 8. The composition of claim 7 wherein the flavoring agents are selected from the
group consisting of peppermint, spearmint and menthol; and wherein the
preservatives are selected from the group consisting of butylhydroxytoluene,
butylated hydroxyanisole, propyl gallate, ascorbic acid, ascorbyl palmitate, sodium
metabisulfite, sodium bisulfite, sodium thiosulfate, sodium hydroxide, cystiene,
25 ethylenediamine tetraacetic acid or salts thereof, citric acid, triethanolamine,
thioglycerol, methylparaben and propylparaben.
 9. The composition of claim 8 wherein the flavoring agent is menthol and
wherein the preservative is butylhydroxytoluene.
 10. The composition of claim 9 wherein each ml of the concentrate comprises
30 about 22.4 mg of sertraline hydrochloride, about 151 mg of ethanol, about 0.50 mg of
menthol, about 0.10 mg of butylhydroxytoluene, and about 1011 mg of glycerin.
 11. The compound, (1S-cis)-4-(3,4-dichlorophenyl)-1,2,3,4-tetrahydro-N-methyl-1-
naphthalenamine methanesulfonate.
- Sub 7
- Sub 8

12. A method of using an essentially nonaqueous, liquid concentrate of sertraline or a pharmaceutically acceptable salt thereof to prepare an aqueous solution of sertraline which comprises diluting the concentrate in an aqueous diluent prior to oral administration.
- 5 13. The method of claim 12 wherein the pharmaceutically acceptable salt of sertraline is the hydrochloride salt or the mesylate salt.
14. The method of claim 12 wherein the diluent is selected from the group consisting of water, orange juice, ginger ale, lemon-lime soda and lemonade.
15. A method of treating or preventing diseases or conditions which are caused by disorders of the serotonergic system which comprises:
- 10 a) diluting an essentially nonaqueous, liquid concentrate of setraline or a pharmaceutically acceptable salt thereof in an aqueous diluent; and
- b) orally administering the resulting aqueous solution to a patient in need thereof.
- 15 16. The method of claim 15 wherein the diluent is selected from the group consisting of: water, orange juice, ginger ale, lemon-lime soda and lemonade.
17. A method of treating or preventing diseases or conditions selected from the group consisting of depression, anorexia, chemical dependencies, anxiety-related disorders, premature ejaculation, cancer and post myocardial infarction, which comprises:
- a) diluting an essentially nonaqueous, liquid concentrate of setraline or a pharmaceutically acceptable salt thereof in an aqueous diluent; and
- b) orally administering the resulting aqueous solution to a patient in need thereof.
- 25 18. The method of claim 17 wherein the anxiety-related disorders are selected from the group consisting of: panic disorder, obsessive-compulsive disorder, generalized anxiety disorder, phobias, post traumatic stress disorder and avoidant personality disorder.
19. The method of claim 17 wherein the diluent is selected from the group
- 30 consisting of: water, orange juice, ginger ale, lemon-lime soda and lemonade.

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